

## REMARKS/ARGUMENTS

### *Status of Claims*

Claims 1, 5-17, 31, 32, 39, 61, 80, and 86 have been amended.

Claims 2-4, and 35-38 are currently canceled.

Claims 18-30, 43-60, 62-79, and 83-85 were previously canceled.

Claim 88 is new.

Thus, claims 1, 5-17, 31-34, 39-42, 61, 80-82, and 86-88 are currently pending in this application.

Applicants hereby request further examination and reconsideration of the presently claimed application.

### *Claim Objection*

Applicants note the Examiner's objection to claim 4 for informalities and respectfully submit that "claim 4" was struck through completely in the Preliminary Amendment. However, Applicants have canceled claim 4 and thus the claim objection of claim 4 is now moot.

### *Claim Rejections – 35 U.S.C. § 112*

Claims 1-17, 31-42, 61, 80-82, 86, and 87 stand rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a 5-HT-receptor agonist, or a pharmaceutically acceptable salt, does not reasonably provide enablement for solvates or derivatives thereof. Applicants have amended the respective claims to remove the phrase "solvates or derivatives thereof" thus rendering the rejection moot.

Claims 5-17, 31, and 32 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Claim 5 has been amended to remove the phrase "any of" and

the term “ambient moisture” thus rendering the rejections to this claim moot. Regarding the rejections to claims 6-17, Applicants have amended the claims to substitute the term “°C” for “EC.” No new matter has been introduced by way of this amendment. Applicants respectfully request withdrawal of the rejections. Regarding claims 31 and 32, Applicants have made the Examiner’s suggested amendments and respectfully request withdrawal of the rejection.

#### ***Claim Rejections – 35 U.S.C. § 102***

Claims 1-3 and 31-34 stand rejected under 35 U.S.C § 102(b) as being anticipated by Patel, et al., U.S. Patent Application Publication 2003/0180352 (hereinafter “*Patel*”). Claims 2-3 and 31-34 depend from claim 1. Thus, the pending claims stand or fall on the application of the cited reference to claim 1. Applicants note claim 35 was not rejected as being anticipated by *Patel*. Consequently, Applicants have incorporated the limitations of now canceled claim 35 into claim 1 and respectfully submit claim 1 and all claims depending therefrom are not anticipated by *Patel*.

#### ***Claim Rejections – 35 U.S.C. § 103***

Claims 1-17, 31-42, 61, 80-82, 86, and 87 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Patel* and Oxford, U.S. Patent No 5,037,845 (hereinafter “*Oxford*”) in view of Remington’s Pharmaceutical Sciences, 1975 (V) (hereinafter “*Remington*”). Applicants respectfully submit the pending claims are patentable in view of the cited references because the broad genus disclosed in the primary reference does not render obvious the Applicants’ instantly claimed subject matter. Applicants’ claim 1 has been amended to incorporate the limitations of now canceled claim 35 and recite:

A pharmaceutically acceptable oral formulation comprising core material which comprises a therapeutically effective amount sumatriptan succinate, which core material is provided with a substantially water resistant coating comprising one or more substantially water resistant materials, wherein said one or more

substantially water resistant materials comprise one or more waxes, or one or more wax derivatives and wherein the coating provides a substantially water impermeable and a substantially moisture impermeable around the core, wherein the core material further comprises mannitol, dibasic calcium phosphate, calcium carbonate, hypromellose, and/or microcrystalline cellulose, croscarmellose sodium and magnesium stearate.

See *supra*, emphasis added. Claim 61 has similarly been amended to incorporate the limitations of claim 35. Applicants respectfully submit *Patel* does not render as obvious the Applicants' claimed species directed to a formulations comprising *a core material comprising the active sumatriptan succinate, and mannitol, dibasic calcium phosphate, calcium carbonate, hypromellose, and/or microcrystalline cellulose, croscarmellose sodium and magnesium stearate.*

#### **The Legal Standard for Obviousness**

The MPEP provides that “establishing a *prima facie* case of obviousness” requires, “the clear articulation of the reason(s) why the claimed invention would have been obvious.” See MPEP § 2142. The MPEP also acknowledges that “[t]he Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit.” See MPEP § 2143. Moreover, in *KSR Int’l Co. v. Teleflex, Inc.*, the United States Supreme Court explained that, “a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art,” but, additionally whether “the claim extends to what is obvious.” See *KSR Int’l Co. v. Teleflex, Inc.*, 82 USPQ2d 1385, 1397 (2007). Further, the rationale for supporting an obviousness determination requires, “choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success.” See MPEP § 2143; see also *KSR Int’l Co. v. Teleflex, Inc.*, 82 USPQ2d at 1397 (a combination of elements is obvious if “there are finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue.”).

**Patel does not present a finite number of identified predictable solutions**

As noted previously, “establishing a *prima facie* case of obviousness” requires, “the clear articulation of the reason(s) why the claimed invention would have been obvious.” See MPEP § 2142. Applicants respectfully submit the Office Action does not provide a rationale for the instantly claimed limitations regarding the components of the core material and as such fails to establish a *prima facie* case of obviousness. Particularly, the Office action asserts “Patel et al teach sumatriptan, mannitol (paragraph 220, 230, 247, and 248) calcium carbonate, dibasic calcium phosphate, microcrystalline cellulose, croscarmellose, sodium, and magnesium stearate (paragraph 248). See Office Action at 13. Applicants note *Patel* discloses compositions that may comprise at least 1500 active materials and at least 200 possible additional components (e.g., surfactants, substrates, solubilizers, antifoamers, etc...) See *Patel* paragraphs [0056]-[0270]. Assuming a simple combination of one active material and one additional component the reference discloses an inordinately large genus that cannot be reasonably said to fairly suggest the Applicants instantly claimed subject matter. The Office Action fails to provide a rationale as to why one of ordinary skill in the art given the benefit of *Patel* would arrive at the Applicants’ instantly claimed **combination** of the active material sumatriptan succinate and mannitol, dibasic calcium phosphate, calcium carbonate, hypromellose, and/or microcrystalline cellulose, croscarmellose sodium and magnesium stearate considering the number of possible combinations disclosed by the reference. Applicants submit that *Patel* cannot serve as the basis for rendering obvious the instantly claimed subject matter because clearly, *Patel*’s recitation of the possibility of innumerable combinations of compounds does not disclose a “finite number of identified, predictable solutions.” See *id*.

Based on the foregoing, Applicants respectfully submit that the Office Action does not present a *prima facie* case of obviousness with regard to the instant claims.

***New Claim***

New claim 88 recites novel and nonobvious aspects of the Applicants instantly claimed subject matter. Support for claim 88 can be found in paragraph [0088] of the instant application. Claim 88 depends from claim 1 and is likewise allowable over the cited references for the reasons set forth previously herein.

**CONCLUSION**

Consideration of the foregoing amendments and remarks, reconsideration of the application, and withdrawal of the rejections are respectfully requested by Applicants. No new matter is introduced by way of the amendment. It is believed that each ground of rejection raised in the Office Action dated May 27, 2009 has been fully addressed. If any fee is due as a result of the filing of this paper, please appropriately charge such fee to Deposit Account Number 50-1515 of Conley Rose, P.C., Texas. If a petition for extension of time is necessary in order for this paper to be deemed timely filed, please consider this a petition therefore.

If a telephone conference would facilitate the resolution of any issue or expedite the prosecution of the application, the Examiner is invited to telephone the undersigned at the telephone number given below.

Respectfully submitted,  
CONLEY ROSE, P.C.

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